




What Is Lean Management in Health Care? Development of an Operational Definition for a Cochrane Systematic Review

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Abstract

Industrial improvement approaches such as Lean management are increasingly being adopted in health care. Synthesis is necessary to ensure

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these approaches are evidence based and requires operationalization of concepts to ensure all relevant studies are included. This article outlines the process utilized to develop an operational definition of Lean in health care. The literature search, screening, data extraction, and data synthesis processes followed the recommendations outlined by the Cochrane Collaboration. Development of the operational definition utilized the methods prescribed by Kinsman et al. and Wieland et al. This involved extracting characteristics of Lean, synthesizing similar components to establish an operational definition, applying this definition, and updating the definition to address shortcomings. We identified two defining characteristics of Lean health-care management: (1) Lean philosophy, consisting of Lean principles and continuous improvement, and (2) Lean activities, which include Lean assessment activities and Lean improvement activities. The resulting operational definition requires that an organization or subunit of an organization had integrated Lean philosophy into the organization's mandate, guidelines, or policies and utilized at least one Lean assessment activity or Lean improvement activity. This operational definition of Lean management in health care will act as an objective screening criterion for our systematic review. To our knowledge, this is the first evidence-based operational definition of Lean management in health care.

Keywords

Lean management, Toyota Production System (TPS), Lean production, operational definition, systematic review

Health-care systems are under pressure to improve patient outcomes using evidence-based interventions (Fine, Golden, Hannam, & Morra, 2009). Many health-care organizations are turning to industrial improvement approaches, such as the Lean Management System (Lean), to enhance quality and safety (Kaplan, Patterson, Ching, & Blackmore, 2014). In health care, these approaches are not yet evidence based (Goodridge, Westhorp, Rotter, Dobson, & Bath, 2015; Lawal et al., 2014; Rotter et al., 2014; Walshe, 2009; Young & McClean, 2008). It is therefore problematic to promote complex approaches or management systems such as Lean in this evidence-informed health-care context. As such, a rigorous, high-level synthesis of primary research is needed to ensure management systems adopted for health care are evidence based. To achieve this, an operational definition is required to objectively identify studies which use Lean

management. This definition is currently lacking as medical literature uses inconsistent terms to describe Lean management (Lawal et al., 2014). Our research team experienced this firsthand while conducting a Cochrane systematic review on the effectiveness of Lean management in health care (Rotter et al., 2017).

Given the lack of an internationally agreed upon definition of Lean management in health care, the development of minimum criteria (operational definition) was essential to differentiate between studies which utilize Lean management and studies which utilize similar interventions (e.g., Six Sigma). This is necessary to ensure that knowledge synthesis includes only studies reflecting the core principles of Lean management, irrespective of the terminology used. This article fills the gap in the literature by proposing the first operational definition of Lean management in health care.

Current Definitions of Lean Management

The evolution (Fujimoto, 2012; Schonberger, 2007), characteristics (Schonberger, 2005; Spear & Bowen, 1999), implementation (Shah & Ward, 2003), and introduction of Lean management into Western organizations (Holweg, 2007) have all been thoroughly documented. However, there is currently debate in the field of operations management (OM) as to what constitutes Lean management. The most frequently cited definition suggests that Lean is “an integrated sociotechnical system whose main objective is to eliminate waste by concurrently reducing or minimizing supplier, customer, and internal variability.” However, a narrative review by Jostein (2009) suggests that there is no consensus definition of Lean management in the literature. Further, there is evidence from OM to suggest that Lean implementation differs between industries (Hines, Holweg, & Rich, 2004). When looking at health care specifically, the definition becomes even more ambiguous, as a recent thematic analysis concluded, “by reviewing the literature, it seems that everything may be Lean” (D’Andrea Matteo, Ianni, Lega, & Sargiacomo, 2015, p.1204). Common definitions of Lean management in health care can be found in Table 1.

Importance of an Operational Definition

Without an agreed upon a definition or inclusion criteria, especially in health care, studies investigating Lean implementation often lack relevant information (Mazzocato et al., 2012) and vaguely refer to Lean management, Lean principles, or Lean thinking (Atkinson & Mukaetova-Ladinska,

Table 1. Common Definitions of Lean Management in Health Care.

Study ID	Characteristics/Definition	Definition Type
Black and Miller (2008)	<p>Patient-centered approach to managing and delivering care that continuously improves how work is done</p> <p>All parts of the production system are focused to eliminate waste while continuously increasing the percentage of value-added work</p> <p>Based on the premise that we can continuously improve health care without adding more money, staff, space, or inventory</p>	Theoretic
D'Andreanmatteo, Ianni, Lega, and Sargiacomo (2015)	<p>Basic principles: Specify value, identify the value stream, avoid interruption in value flow, let customers pull value, and start pursuing perfection again</p> <p>Other principles: Committed management, respect for people, and the involvement of supply chain management</p> <p>Prioritizing flow efficiency over resource efficiency</p>	Theoretic
Glasgow, Scott-Caziewell, and Kaboli (2010)	Articles that self-identify as reporting on a Lean, Six Sigma, or Lean Sigma projects	Operational
Mazzocato, Savage, Brommels, Aronsson, and Thor (2010)	<p>Understand processes to identify and analyze problems</p> <p>Organize more effective and/or efficient processes</p> <p>Improve error detection, relay information to problem solvers, and prevent errors from causing harm</p> <p>Manage change and solve problems with a scientific approach</p>	Theoretic
Poksinska (2010)	Understanding what adds value and how to eliminate waste. Often emphasizes that current health-care systems consist of fragmented processes that require a shift in how the flow of patient care delivery is	Theoretic

(continued)

Table 1. (continued)

Study ID	Characteristics/Definition	Definition Type
Radnor, Holweg, and Waring(2012)	perceived and organized	Theoretic
	Recognizes the patient as the primary customer and as a critical factor to be taken into consideration when designing processes and delivering care	
	Sees the processes as they are performed with all problems and shortcomings	
	The philosophy of continuously improving processes by increasing customer value or reducing nonvalue adding activities (muda), process variation (mura), and poor work conditions (muri)	
	Assessing activities that include reviewing the performance of existing organizational processes to look at waste, flow, or capacity to add value	
	Improvement activities that support and improve processes	
	Performance monitoring to measure the processes and any improvements made	

2012; G. Smith, Poteat-Godwin, Harrison, & Randolph, 2012; Van Vliet et al., 2011; Vegting et al., 2012).

This article describes the process and outcomes related to creating an evidence-informed operational definition of Lean health-care management. An iterative process of testing, updating, and retesting the criteria was used to identify relevant characteristics; this approach has been suggested by Kinsman, Rotter, James, Snow, and Willis (2010) and Wieland, Manheimer, and Berman (2011).

It is important to note that this process was used to develop an operational, rather than a theoretical, definition. A theoretical definition characterizes the fundamental nature of a construct. In contrast, an operational definition provides a concrete test to determine whether or not a specific

example falls within that construct (Wieland, Manheimer, & Berman, 2011). This difference is illustrated by Wieland et al. (2011) who provide the example of a randomized control trial for depression medication. In such a trial, the theoretical construct of the disease being treated is “depression,” but the operational definition may be a score of 20 or more on the Beck Depression Inventory or answering “yes” to the question “Are you depressed?” As such, the operational definition brings practical use to a theoretical construct. The need for an operational definition of Lean is supported in a review by Bhamu and Sangwan (2014), which identified 33 definitions of Lean used in OM. Since all of the definitions were theoretical, rather than operational, they could not be applied as content inclusion criteria.

Method

The literature search strategy, screening, data extraction, and data synthesis followed the Cochrane Effective Practice and Organisation of Care (EPoC, 2008) methods used in systematic reviews. The development of the operational definition utilized the methods of Kinsman et al. (2010) and Wieland et al. (2011).

Kinsman et al. (2010) describe four steps to develop an evidence-informed operational definition of clinical pathways: (1) identify relevant publications on theoretical definitions, (2) synthesize similar components and develop draft criteria, (3) test the criteria, and (4) modify and retest the criteria. Wieland and colleagues (2011) propose two major steps to develop an operational definition of complementary and alternative medicine for the Cochrane Collaboration: (1) develop an operational definition by using relevant and available theoretical definitions and (2) test the application of the operational definition to identify relevant studies. Both approaches use similar methods to achieve the same goal, differing only in the way steps are described and categorized.

Literature Search

We developed a search strategy (Online Supplemental Content File 1) for OVID MEDLINE and searched from database inception on 1946 to December 2013. The strategy was comprised of key word phrases since there were no Medical Subject Headings to describe Lean management in health care. The search phrases included the word “Lean” in proximity to a group of synonyms aimed at identifying management processes (e.g., organization,

management, process, and technique). This search was the first stage in the iterative process of developing a search strategy for our systematic review. At this point, the search strategy was not intended to identify all applications of Lean management.

Screening Methods

Primary studies were initially included or excluded using the definition and inclusion criteria published in the systematic review protocol (Lawal et al., 2014). The population, intervention, comparison, and outcomes used as inclusion/exclusion criteria in the protocol are presented in Online Supplemental Content File 2.

Titles and abstracts of search results were screened for inclusion independently by two authors. Disagreements were resolved by discussion or by a third author. After title and abstract screening was completed, the full text of the remaining primary articles was retrieved and assessed.

Data Synthesis and Criteria Development

The four steps of Kinsman et al. (2010) were followed to develop and test an evidence-based operational definition of Lean management.

The first stage followed the Cochrane EPOC (2008) method as two authors independently extracted all data regarding the description of Lean interventions, the use of Lean management in the organization, and the characteristics of the organizations described in each study. Extraction results were compared, and disagreements were resolved by discussion.

In the second stage, the authors synthesized similar components in tabular and narrative form, categorized them, and drafted minimum inclusion criteria on Lean in health care as an operational definition for the Cochrane review.

In the third stage, the authors iteratively tested the criteria for the operational definition. At this stage, the operational definition was applied to all primary articles to assess coherence between the criteria developed and the concepts reported in the primary articles. Following this application, the definition was updated to address any apparent shortcomings. To determine whether our final iteration of the operational definition was clear and could be applied consistently, we tested interrater reliability by calculating Cohen's κ (K) for full-text screening results. A K value over 0.75 was considered excellent, 0.40–0.75 as fair to good, and below 0.40 as poor (Viera & Garrett, 2005). Results were calculated for screening results prior

to discussing conflicts. Statistical analysis was conducted using SPSS Version 24 (International Business Machines Corporation, 2016).

In the fourth stage, the operational definition was reapplied to all previously identified search hits (titles, abstracts, and full-text articles). Results utilizing the refined operational definition were compared with results of the original screening process to determine the extent to which screening results changed due to the newly developed operational definition of Lean management in health care.

We also extracted data regarding the sustainability of Lean in the organizations described in each of the included primary articles. This was important as Lean management is a relatively new phenomenon in health care (Brandao de Souza, 2009) and implementation is still in its infancy, a stage similar to that of automotive manufacturing in the 1990s (Radnor, Holweg, & Waring, 2012).

We represent the sustainability of Lean systems by capturing the duration of the follow-up period reported. This was measured in months and was calculated as the period between the conclusion of the specific Lean intervention and the latest date on which an outcome was measured.

Results

Literature Screening

The MEDLINE search identified 511 records, with two additional records identified via hand searching. Ten duplicates were identified, leaving 503 records. During the title and abstract screening phase, 371 records were excluded as they did not meet the inclusion criteria. The full text of the remaining 132 references was examined, and 33 studies were selected for inclusion. The list of included studies can be found in Online Supplemental Content File 3. The flowchart for this process is presented in Online Supplemental Content File 4, and decisions for each article can be found in Online Supplemental Content File 5.

Data Extraction

Two authors independently extracted the descriptions of Lean interventions used in each of the 33 primary articles. Results of this process showed that 27 articles mentioned some aspect of Lean thinking, Lean philosophy, or Lean-based continuous improvement throughout the organization or a sub-unit of the organization; 26 studies described the use of value-stream

mapping (VSM); 15 studies illustrated the use of a Rapid Process Improvement Workshop (RPIW); 7 studies utilized sort, sweep, simplify, standardize, and sustain/self-discipline (5S) methodologies; 6 studies reported the use of Gemba walks; 4 depicted standard work; 3 studies reported A3 problem-solving; 3 studies utilized leveled production; 3 studies illustrated the use of daily visual management (DVM); and 2 studies applied stop the line techniques. Details regarding the methods and Lean activities used in each study can be found in Table 2.

Data Synthesis

Based on the extracted information, we summarized key characteristics into two themes that encompass the defining elements of Lean management in health care: Lean philosophy (characterized by Lean principles and continuous improvement) and Lean activities (characterized by assessment and improvement activities). These themes underpin the definition developed and are operationalized in the following list:

- *Lean philosophy* is a set of ideas at the center of Lean. Lean philosophy is made up of Lean principles and continuous improvement:
 - *Lean principles* refer to an overarching set of principles aimed at transforming workplace culture (Kruskal, Reedy, Pascal, Rosen, & Boiselle, 2012). These include a focus on eliminating waste (DelliFraine, Langabeer, & Nembhard, 2010; Mazzocato, Savage, Brommels, Aronsson, & Thor, 2010; Poksinska, 2010); improving the flow of patients, providers, and supplies (Black & Miller, 2008; Holden, 2011; Poksinska, 2010); and ensuring all processes add value to customers (Kim, Spahlinger, Kin, & Billi, 2006). Further, Lean principles suggest that problems are identified and addressed by frontline staff members as it is believed that the people doing the work are best suited to create solutions (Casey, Brinton, & Gonzalez, 2009; Holden, 2011; Kruskal et al., 2012).
 - *Continuous improvement* refers to the acknowledgment that Lean does not occur as a single intervention but instead requires ongoing efforts and interventions aimed at improving the workplace (DelliFraine et al., 2010; Holden, 2011; Mazzocato et al., 2010).
- *Lean activities* are a set of management practices, tools, or techniques that can be directly observed and are prescribed to improve

Table 2. Lean Methods Used in Each of the 33 Primary Articles.

Study ID	Lean Philosophy	Lean Assessment Activities				Lean Improvement Activities			
		A3	Gemba Walk	RPIW	VSM	5S	Stop the Line Techniques	Leveled Production	Standard Work
Atkinson and Mukaetova-Ladinska (2012)	x			x					
Barnas (2011)	x	x		x					x
Beard and Wood (2010)					x				
Biffi et al. (2011)	x	x		x					
Blackmore, Bishop, Luker, and Williams (2013)	x			x			x		
Cankovic et al. (2009)	x				x	x			x
Chiodo et al. (2012)	x			x	x		x	x	
Cima et al. (2011)	x		x						
Collar et al. (2012)	x				x				
Fischman (2010)					x				
Ford et al. (2012)	x				x				
Grove, Meredith, Macintyre, Angelis, and Neailey (2010)	x				x				
Harmelink (2008)					x				
Hummer and Daccarett (2009)	x		x		x	x			
Kelly, Bryant, Cox, and Jolley (2007)					x				
King, Ben-Tovim, and Bassham (2006)	x				x				
McDermott et al. (2013)	x			x	x				
Melanson et al. (2009)	x			x	x				
Michael, Naik, and McVicker (2013)	x			x					
Morrison et al. (2011)	x				x			x	

(continued)

Table 2. (continued)

Study ID	Lean Assessment Activities					Lean Improvement Activities				
	Lean Philosophy	A3	Gemba Walk	RPIW	VSM	5S	Stop the Line Techniques	Leveled Production	DVM	Standard Work
Murrel, Offerman, and Kauffman (2011)	x				x					
Naik et al. (2012)	x			x	x	x				
Ng, Vail, Thomas, and Schmidt (2010)	x			x	x					x
O'Neill, Jones, Bennett, and Lewis (2011)	x		x	x		x			x	
Piggott, Weldon, Strome, and Chochinov (2011)	x			x	x					
C. Smith, Wood, and Beauvais (2011)	x				x					
M. L. Smith, Wilkerson, Grzybicki, and Raab (2012)	x		x	x	x	x				
G. Smith, Poteat-Godwin, Harrison, and Randolph (2012)	x	x	x	x	x					
Ulhassan et al. (2013)	x				x	x		x	x	
van Lent, Goedbloed, and van Harten (2009)					x			x		
Waldhausen, Avansino, Libby, and Sawin (2011)	x			x	x	x				
Yerian, Seestadt, Gomez, and Marchant (2012)	x		x	x						x
Yousri, Khan, Chakrabarti, Fernandes, and Wahab (2011)					x					
Total	27	3	6	15	26	7	2	3	3	4

Note. A3 = A3 problem-solving; RPIW = rapid process improvement workshop; VSM = value stream mapping; 5S = sort, sweep, simplify, standardize, and sustain/self-discipline, DVM = daily visual management.

the workplace. There are two types of Lean activities: assessment activities and improvement activities.

- *Lean assessment activities* work as analytic tools to identify waste and areas of possible improvement. These activities allow team members to see problems and identify opportunities to reduce waste and make improvements but do not prescribe specific solutions. Lean assessment activities include VSM, spaghetti diagrams, RPIWs, Gemba walks, and root cause analysis.
- *Lean improvement activities* suggest specific ways to reduce waste, improve the workplace, and set up new working practices. These include actions and concepts such as 5S events, leveled production, DVM (including Kanban supply management), standard work, and stop the line techniques.

Operational Definition

Based on the themes identified, we created an operational definition of Lean management in health care that will act as an objective screening criterion for our systematic review. The resulting operational definition requires that included studies describe an organization or subunit of an organization (e.g., department or ward) which

1. integrated Lean philosophy into the organization's mandate, guidelines, or policies and demonstrated by (1a) evidence of Lean principles and (1b) evidence of continuous improvement; and
2. utilized at least one Lean activity and demonstrated by (2a) evidence of a Lean assessment activity or (2b) evidence of a Lean improvement activity.

Evidence of (1a) Lean principles was considered sufficient where there was an explicit statement that the organization had adopted Lean management or an in-house system based on Lean (e.g., the Virginia Mason production system) or a management system which explicitly incorporates the following three components: reducing waste, improving flow, and utilizing an employee-driven approach to improvement. Evidence of (1b) continuous improvement was considered sufficient when there was a statement asserting that the organization had created a dedicated quality improvement team/unit or that the organization conducted at least two distinct quality improvement projects including any projects described in the article.

Evidence of Lean activities was considered sufficient when the study described the use of (2a) a Lean assessment activity (e.g., VSM, spaghetti diagrams, RPIWs, Gemba walks, or root cause analysis) or (2b) a Lean improvement activity (e.g., 5S events, leveled production, DVM, standard work, or stop the line techniques) or both. A screening form demonstrating how the operational definition will be used can be found in Table 3.

Testing of Operational Definition

In order to test the coherence between the 33 primary studies and the operational definition, the definition was applied to each of the studies identified. Results indicated that 27 of the 33 studies fit well with the criteria and were included based on this definition. The remaining six studies were excluded due to their failure to demonstrate integration of Lean philosophy. Information regarding changes in inclusion status can be found in Online Supplemental Content File 3. Additional information regarding excluded studies is available in Online Supplemental Content File 6. Of the 27 included studies, 15 reported only a Lean assessment activity, 11 reported both assessment and improvement activities, and 1 study reported using only a Lean improvement activity. As noted, details on activities used are presented in Table 2.

Study Selection After Applying Operational Definition (Rescreening)

All 511 search results were rescreened based on the operational definition presented above. During the title and abstract rescreening phase, 367 records not meeting the inclusion criteria were excluded. Full-text assessment of the remaining 136 records resulted in selecting 43 studies. This process excluded six previously included studies and included 16 previously excluded studies. Details on newly included and excluded studies can be found in Online Supplemental Content File 3. The flowchart for this process can be found in Online Supplemental Content File 7, and decisions for each article can be found in Online Supplemental Content File 8.

Interrater Reliability

Screening results for full-text articles led to a consensus to include 43 studies and exclude 77 studies with disagreement on 16 studies prior to discussion. These results suggest approximately 88% agreement. Statistical

Table 3. Screening Form Utilizing the Operational Definition.

Screening Form			
Minimum Inclusion Criteria for Lean Management			
Reviewer Name:			
1a	Has the organization or subunit of the organization integrated Lean principles? (Demonstrated by an explicit statement that the organization has adopted Lean management or an in-house system based on Lean [e.g., the Virginia Mason production system] or a management system that explicitly incorporates the following three components: reducing waste, improving flow, and utilizing an employee-driven approach to improvement)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	Source of information (page number):
1b	Has the organization or subunit of the organization integrated continuous improvement? (Demonstrated by the creation of a dedicated quality improvement team/unit or a statement asserting the organization conducted at least two distinct quality improvement projects including any projects described in the article).	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	Source of information (page number):
2a	Did the intervention include at least one Lean assessment activity?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	Source of information (page number):
2b	Did the intervention include at least one Lean improvement activity?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unclear	Source of information (page number):
<p><i>Eligibility:</i></p> <p>Criterion 1a “Yes” and Criterion 1b “Yes” and Criterion 2a or Criterion 2b must be “Yes”</p>			
Decision:		<input type="checkbox"/> Include <input type="checkbox"/> Exclude	

testing suggested excellent agreement between judgments, $K = 0.753$, $p < .001$. Following discussion, agreement was reached for all 136 studies.

Lean Sustainability

Of the 43 articles selected during the rescreening phase, 11 studies reported a follow-up of 6 months or less, 18 reported a follow-up of 7–24 months, 5 reported a follow-up of more than 2 years, and 9 failed to provide adequate information to determine length of follow-up. Additional details can be found in Online Supplemental Content File 9.

Discussion

The operational definition developed fits well with the current literature and acts as an objective inclusion criterion. However, some limitations became apparent during its application. First, the articles on which the definition is based may describe organizations which have only recently adopted Lean. Second, it is sometimes difficult to distinguish *assessment* from *improvement* activities.

Coherence With the Literature

The definition developed fits well with the current literature, operationalizing many of the characteristics identified in previous reviews. The Lean activities identified are similar to those reported in the work by Radnor, Holweg, and Waring (2012), which identifies “assessment activities,” “improvement activities,” and “performance monitoring activities.” However, we did not identify the “performance monitoring activities” described by Radnor et al. This may have resulted from the fact that only four studies from the original screening phase and five studies from the rescreening phase provided follow-up data for more than 24 months.

Further, the Lean characteristics identified in this article align well with the work of Poksinska (2010), which describes the steps of Lean implementation as “focusing on the patient as the primary customer” (“patient orientation”), “learning to see process shortcomings,” and “specifying how work should be done.” In this case, “patient orientation” is comparable with the integration of “Lean principles,” while “learning to see process shortcomings” and “specifying how work should be done” are analogous to “assessment activities” and “improvement activities,” respectively. Finally, parallels can be seen between “Lean philosophy” and “Lean activities” and

the work of Hines, Holweg, and Rich (2004), which notes that Lean exists at both the “strategic” and “operational” levels.

It is also interesting to note that the priorities identified in the operational definition only partially overlap with those presented in much of the OM literature. For example, the focus on including frontline staff, committing to continuous improvement, and utilizing standard work mesh well with the concepts of total quality management and human resource management outlined by Shah and Ward (2003); however, we found little emphasis on just-in-time systems and total productive maintenance.

Similarly, the integration of “continuous improvement” and “Lean principles” is in line with the areas of “Lean implementation” and “workforce management” identified by Papadopoulou and Ozbayrak (2005). Further, the “Lean activities” we identified seem to focus on the “product/process-oriented” and “production, planning, scheduling, and control” areas described by Papadopoulou and Ozbayrak. In contrast, “production floor management” and “supply chain management” appear deemphasized. Exploration of the reasons for these differences is outside the scope of this article, but we hope to focus on this area in subsequent publications.

Sustainability and Study Type

Among all the studies utilized in the development of the operational definition, only four had follow-up periods greater than 24 months. Furthermore, all studies identified were empirical studies rather than theoretical or conceptual articles. As a result, the studies captured are likely to be focused on the process of implementing Lean interventions rather than providing a conceptual framework for Lean. Taken together, these points suggest that the operational definition developed best describes organizations in the early stages of Lean implementation. As such, future research will be needed to determine whether the definition is applicable to organizations which have been utilizing Lean for an extended period of time.

Lean Assessment and Improvement Activities

The issue of an imperfect distinction between assessment and improvement activities results from the fact that characterizations were made based on the primary nature of each activity. However, many Lean activities include both assessment and improvement components. This can be seen in 5S events, where the “sort” component requires team members to identify and

eliminate unneeded tools, parts, or supplies, thereby acting as an assessment activity. In contrast, the “set in order” and “standardize” components dictate that items should have a standardized location and that these locations should be visually represented; therefore, these components act as a Lean improvement activity.

Importance of an Operational Definition

The application of the operational definition to the 511 search hits unambiguously illustrates the importance of having a clear operational definition for systematic reviews. Without using the operational definition, 16 relevant studies would have been missed and 6 irrelevant studies would have been included. This resulted in a net increase of 10 studies (23% of included studies). It is noteworthy that applying the operational definition resulted in a substantially higher number of studies included (43 studies) as compared to 33 studies included using the definition and inclusion criteria published in the systematic review protocol (Lawal et al., 2014). It is also important to note that the operational definition developed showed an excellent level of agreement, demonstrating consistent application.

The relatively weak definitions relating to Lean were also obvious in the way Lean methods were reported in the literature. One major shortcoming identified was that many authors did not have a standard template outlining which components of an organization’s use of Lean should be described. This was most obvious in reporting of Lean philosophy as it was unclear whether some organizations had integrated Lean philosophy or whether the intervention was a single “Lean-inspired experiment.” For this reason, six of the originally included studies were excluded. This is a necessary distinction as Lean is an overall management system rather than a set of tools (Bhasin & Burcher, 2006). Many tools such as VSM, spaghetti diagrams, and root cause analysis are not unique to Lean and are used in other continuous quality improvement approaches. As such, it is hoped that this operational definition will help improve reporting of Lean interventions used in health care.

Limitations and Next Steps

The first limitation is the fact that management systems evolve and definitions change over time; it is therefore crucial to understand that operational definitions must evolve over time. This is the first publication in this iterative process of definition development. As such, once we have completed

our systematic review, we will work toward a subsequent publication further testing and refining this operational definition. The ensuing paper will include calculations on sensitivity and specificity of the applied working definition. In addition, we will report the reasons for inclusion (as quotes from the studies) as well as the reasons for excluding studies in the final Cochrane review. The latter will be noted in a section titled “Characteristics of Excluded Studies.”

A second limitation can be found in the early nature of our operational definition. We searched for Lean investigations captured in OVID MEDLINE from 1946 to 2013. This pilot search will be updated and extended to all relevant databases for our full systematic review on Lean. In light of these first two limitations, our aim is for the current definition to be utilized to screen studies, to inform debate on Lean management, and to stimulate other researchers to use the definition in future reviews in addition to further testing and refining it.

The final limitation comes from the fact that this is an operational rather than theoretical definition. It is consequently meant to be applied in systematic reviews to catalogue and report on the current experience of Lean in health care. We do not aim to propose a uniform and theoretical definition.

Conclusion

This article outlines the process utilized to develop, test, and apply an operational definition of Lean management in health care. To our knowledge, this is the first data-driven operational definition of Lean in health care developed to date. Although there are other theoretical definitions, they do not outline specific criteria for whether or not an intervention falls within the scope of Lean management.

This process proved beneficial as it helped to ensure the screening process captured all relevant studies while simultaneously eliminating irrelevant studies, thus demonstrating the importance of a well-defined operational definition in guaranteeing unbiased knowledge synthesis. However, the definition developed through the process has the potential to be biased toward organizations in the early stages of Lean implementation. To develop an accurate definition, it is necessary to capture studies which include organizations throughout a range of management phases. Unfortunately, the literature in this respect is limited. It is hoped that the operational definition of Lean management in health care developed in this article will act as a first step in solidifying the definition, conceptualization, and quality of reporting regarding Lean in health care.

Researchers and clinicians who face the task of identifying and synthesising Lean research should further apply the proposed definition in order to test and refine our Lean criteria and to utilize the definition in future systematic reviews. This crucial step helps to increase rigour and transparency while decreasing variation; this in turn will help to build a strong and replicable evidence base for future decision makers.

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Supplemental Material

Supplementary material for this article is available online.

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